IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

DePuy Mitek's Motion to Strike Certain Improper Expert Testimony of Dr. Stephen Burkhart

Mitek respectfully moves the Court to strike portions of Dr. Stephen Burkhart's testimony as improper expert testimony. Dr. Burkhart was offered as a fact witness only, not as an expert. In fact, Arthrex's counsel submitted a declaration to the Court stating the same. Further, Dr. Burkhart did not submit a Rule 26 expert report. For these and other reasons stated below, any expert testimony from Dr. Burkhart is improper and Mitek moves the Court to strike Dr. Burkhart's expert testimony found on pages 457:13- 459:24 of the trial transcript.[1]

Mr. Saber, Arthrex's counsel, represented to the Court through a declaration that Dr. Burkhart would not testify as an expert and would testify to his role in the development of FiberWire. (Ex. 2 at ¶¶2 & 6). But Dr. Burkhart testified beyond this limited scope. His testimony included answers to questions such as "what would happen if you had poor tissue drag" in a suture and how "speed relate[s] to the other friction points [in the tissue.]" Because

[1] Mitek attaches these portions of the transcript as Exhibit 1 to this motion to strike.

his answers were not limited to his surgical experience, but rather, related to potential surgical consequences of surgeons in general using a theoretical suture having poor tissue drag, this testimony is improper expert opinion testimony and should be stricken. FED. R. EVID. 701. Mitek's counsel objected to the expert nature of Dr. Burkhart's testimony, and when Judge Saris understood the nature of the objection, she shut it down (Ex. 1 at 451:11-12; 455:8-9; 459:25).

Indeed, Arthrex has recognized this as expert testimony because Dr. Burks, Arthrex's surgeon expert who is appearing by videotape at trial, expressed opinions about similar subject matter in his expert report. Specifically, Dr. Burks stated in his expert report "I may describe the characteristics of a surgical suture that are generally important to an orthopedic surgeon." (Ex. 3 at ¶6). In Dr. Burks' absence, Arthrex improperly attempted to bring this expert testimony in through Dr. Burkhart, a fact witness. If Arthrex intended on using Dr. Burkhart as an expert, Arthrex should have timely disclosed him as an expert and should have submitted an expert report with his opinions. Arthrex did neither. Further, Arthrex's belated attempt to use Dr. Burkhart as an expert prejudices Mitek because it did not have the benefit of an expert report disclosing these opinions and did not have the opportunity to cross examine him about them at deposition.

For these reasons, Dr. Burkhart's improper expert testimony on pages 457:13- 459:24 should be stricken from the record.

Dated: August 13, 2007

DEPUY MITEK, INC.,
By its attorneys,

/s/ Erich M. Falke

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CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

DePuy Mitek's Motion to Strike Certain Improper Expert Testimony of Dr. Stephen Burkhart

were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date *via* the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

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Dated: August 13, 2007

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., a Massachusetts Corporation, Plaintiff
-VS-
ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants

CA No. 04-12457-PBS
Pages 430 - 522

JURY TRIAL - DAY FOUR

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania, 19104-2891, for the Plaintiff.

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 20006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 10, 2007, 9:00 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
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bumpy, and it has a lot of friction. It has, you know, a high coefficient of friction relative to other types of suture; for example, the monofilament, which is just a single strand and doesn't have a lot of friction to it. So you have to have some way to smooth out the bumps, and a coating is a very tried and true tested type of way to do that.

Q. Now, I think you mentioned sliding through suture. Could you explain to the jury what that is? Sliding the suture and sliding through suture, you used a couple terms there.

MS. ELDERKIN: Objection. Expert.

THE COURT: Overruled.

Q. Go ahead, you can answer.

A. Well, the suture has to slide actually through a number of different interfaces. It has to slide against each other, so, you know, when you tie a knot, you have two suture strands. So if you have one braided suture strand against another suture strand, if they have a very high friction and a lot of bumps, you're not going to be able to slide them as well.

They also have to slide through soft tissue, so you're pulling your suture through, for example, tendon; and if it's too bumpy, it actually tends to cut the tendon. In fact, there are some mechanical saws that are based on that principle of having bumps on them. They actually can even

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saw through bone.

And, in addition, it has to pass through various things like cannulas. It has to pass through a plastic cannula. It has to pass through the eyelets of the anchor as you pull through. It has to pass through the openings in the suture pass-throughs that it draws in the suture passer. So you hit friction every step of the way.

Q. Dr. Burkhart, I know that may be a little bit complicated for the jury. Could I ask you to just step down and perhaps draw on the easel some examples of what you may be speaking about. I'm just going to move this over here. We'll try and get it so the Judge can see and the jury can see, and the lawyers too.

A. Okay. Well, I'm not really an artist, not even close, but I'll do my best here.

THE COURT: Do you know what I think? Even though it might be an issue for me, if you got a little closer to the jury. I think I'll move down. I don't know that people can necessarily see it.

(Witness at easel in front of jury.)

A. So let's use an example of a torn rotator cuff. This would be the humerus, which is the bone. Basically you've got bone here. And then you've got your rotator cuff which is torn loose from the bone, which would be -- you've got muscle out in this area but then tendon here, which is that

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gristly fibrous tissue. And you've got to reattach this down to the bone where it's pulled away from. It's actually torn away from the bone.

So the way you do that is, you have a suture anchor, which is something, for example, a biodegradable screw that has an eyelet to it here with sutures attached to it. You have to remember the skin is out here too. It's kind of like building a ship in a bottle. So you've got to start at a distance, and then you have to -- you have to start outside where you can handle things, deliver them inside at a distance. So you have to have ways to do that, and you're working through cannulas, little tubes that your instruments can go through.

Okay, so basically you're going to have sutures here, so we'll draw one limb of the suture that's out here. This limb you're going to have to pass through the tendon, and you're going to have a small instrument that either pulls it through or that pushes it through. So let's say that we have what we call a retrograde pass-through that comes through, and it has a jaw to it, and it has something like this, a little hook so that it grabs it and pulls it through. So there's going to be friction created between the jaws of the instrument and the sutures so it pulls it through.

Then you're going to grab this with another passer

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and pull this suture limb out here through the cannula. So it has friction coming through the cannula because there has to be a little rubber diaphragm here to prevent the fluid from all escaping.

So then what you do is, you tie a knot. You'll bring your two suture limbs together, and you'll have a very complex sliding knot, but you'll have a lot of surface area between the sutures and the weave back and around, but still be able to push the knot down. But you can't have so much friction that the knot stops halfway down, or then you've lost your fixation, you don't have any fixation. So you have friction at this point.

You have a knot pusher as well. Typically it's a little tubular thing with a hole in it -- we call it a cannulation -- that pushes your knot down and helps you with that. And then once this base knot is down, then you have to throw some more half hitches, which are some additional throws that come down on the top.

So the frictional points that you have really, they're going to have friction at your eyelet here. You're going to have friction coming through the jaws of your instruments. Every time you pass it, you can have friction through the soft tissue, which if it's too rough, potentially your suture will just cut through the soft tissue and destroy a part of your soft tissue, which is the worst possible

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scenario. You have friction here between the suture and your instrument, and then you have major friction here between the two limbs of your sutures. So that pretty much sums it up, I think.
Q. Okay, just to help the jury a little bit, Dr. Burkhart, could you just mark on your drawing the places where the friction occurs and just what they are.
MS. ELDERKIN: Objection. Expert testimony.
THE COURT: Overruled.
Q. Go ahead, you can do that, sir.
A. Okay, so friction occurs here where the red is at the eyelet. It occurs here where the suture is passing through the instrument.
Q. And could you just write down some words for the jury.
A. Oh, okay, sure. Okay, so friction. So at the eyelet of the anchor, and it would occur at the jaws of the instrument. It would occur at the soft tissue. It would occur at the cannula, which is this tube that it passes through. And it would occur at the knot where it's suture against suture. And it would also occur at the knot pusher, at the interface between the knot pusher and the knot.
As I get lower, I'm getting more and more like a doctor's handwriting there too. Okay.
Q. And could you just mark, I guess, in red, just to complete the drawing, the friction points, just so that we

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know where they are.
A. Okay, here, here, here. There would also have to be an instrument this side coming in. That would be another suture retriever to grab that suture, so it would be another one with a jaw like that. So that would be another friction point. And there, there, both ends of the cannula, and then the suture against suture and then knot pusher against suture.
Q. Thank you.
MR. SABER: Your Honor, I'd like to mark Dr. Burkhart's drawing as Exhibit 1377.
THE COURT: As an exhibit?
MR. SABER: Yes. This is what he created in court.
MS. ELDERKIN: Objection.
THE COURT: Sustained.
MR. SABER: Thank you. Let me move this back and --
THE COURT: You know, witnesses are allowed to teach you, and both sides have done that by drawing you pictures. In the olden days, we actually called them "chalks." When I started as a judge, they were literally done on a chalkboard, but now we have all this high-tech stuff. So this is to help you to understand, but it's not an exhibit in the sense that an accurate picture is, and that's sort of that little debate we were just having. So you can

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use it to help understand the issues, but it is not an exhibit. It's obviously not an exact replication of tissue and the like.
(Witness resumes the stand.)
Q. Now, one of the things I think you told the jury a bit about was as the suture was going through tissue. Have you heard the term "tissue drag"?
A. Yes.
Q. Does that relate to what you were telling about the suture going through tissue?
A. Right. It just relates to the friction of the suture as it comes through the tissue.
Q. Okay. And can you explain to the jury what would happen if you had poor tissue drag?
A. If you have excessive drag with more friction, then you worry about it actually cutting the soft tissue, and that's something that surgeons are faced with quite often. Particularly, if you can imagine someone has a rotator cuff tear anyway, they're going to have rather poor tissue relative to someone who's healthy; and then if you're going to challenge it even further by having suture with a lot of drag and you potentially tear that tissue in half, then you may end up with a situation where you just can't repair it.
Q. Now, when you discussed the need for coating with Mr. Grafton, what relationship did that have to these

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friction points that you testified about?
A. Well, it had everything to do with it because as a surgeon in the operating room, you've got to have -- you can't tolerate a high-friction suture. You just can't tolerate it. You have to have enough friction to hold the knot. You have to have enough pliability that it turns back on itself, but you have to have something that slides and doesn't damage tissue.
Q. Now, these issues that you spoke about, are they important to you as an orthopedic surgeon?
A. Absolutely.
Q. And could you explain to the jury a bit why they're important to you.
A. Well, you know, speed is important for a lot of reasons. Obviously, you want a surgeon who's meticulous, but you want a surgeon who can do it on a timely basis as well because speed is important. In fact, if you look at things like infection, the one factor that has always been related to infection has been length of operation, and the longer the operation, the higher the chance of infection. So that's just one thing that's drilled into you as you're going through your surgical training. But speed is important. If you can reduce the length of the operation, you reduce the chance of infection, you reduce the chance of complications from anesthesia. It all adds up.

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There are even some -- well, if you look at -- I guess when you're looking at speed also, I understand that the FDA actually, if certain things take too long, that you can lose FDA approval on certain things.

But I think one of the biggest things still in terms of, it's not just speed where you'd want to reduce the tissue drag, but you also want to reduce the damage to tissues.

Q. And does speed relate to the other friction points that you spoke about as well?

A. Absolutely. You know, I've estimated that to do, for example, an arthroscopic rotator cuff repair, there are about 350 to 360 different manipulations you have to do. Each manipulation is about 20 seconds, so if you can save five seconds per manipulation, it's huge. That's 30 minutes right there. But it's, you know, six minutes per manipulation for almost 360, so if you can significantly -- and, you know, decreasing the amount of drag is a big part because a big part of the time you're spending is tying knots, and you have multiple manipulations for each knot.

Q. Now, if the difference between one suture and another suture, the difference in how smooth it is is just a little bit, does that make a difference to you as an orthopedic surgeon?

MS. ELDERKIN: Objection. Expert testimony.

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THE COURT: Can I see you at side bar.

SIDE-BAR CONFERENCE:

THE COURT: It may be I'm not understanding it, but he seems to have the expertise.

MS. ELDERKIN: He didn't put in an expert report.

THE COURT: It wasn't clear what the objection was. It sounded as if you're challenging qualifications.

MS. ELDERKIN: He has no expert report, and when we filed a motion to exclude him, Mr. Saber represented in the declaration he's not being brought to testify as an expert.

MR. SABER: When he had these conversations with Mr. Grafton, and we'll get into the killer idea in a moment, he has to explain what he meant by it and why he told Mr. Grafton what he told him.

MS. ELDERKIN: This is expert testimony.

THE COURT: I wish I had understood the basis for your objection better. I thought you meant he didn't have the expertise to say it. He certainly does have the expertise to say it.

MR. SABER: I'm almost done with it.

THE COURT: Now that I understand it, move on.

(End of side-bar conference.)

Q. Now, Dr. Burkhart, did there come a time when you had an E-mail exchange with Mr. Grafton about some of the ideas Mr. Grafton had for FiberWire?

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A. Yes.

Q. And in that E-mail exchange, did you refer to some of his ideas as a "killer idea"?

A. Yes.

Q. And when you made those comments to Mr. Grafton, were you conveying that the suture did not have to be coated?

A. No.

Q. Okay, could you explain why you say that?

A. Well --

THE COURT: Say what, "killer idea"?

MR. SABER: No, why he wasn't saying that it didn't have to be coated.

A. Well, as we'd said from the very beginning --

MR. SABER: Say that it had to be coated. I'm sorry, your Honor.

A. Too many negatives in there.

Q. Sure.

A. From the very beginning when we tie tested that first uncoated product or uncoated prototype, I talked to Don and said, you know, "Do these have to be coated?" and he said, "Well, of course." I mean, that was understood from the beginning because you have to have something that has a low enough coefficient of friction that you can tie a knot that is secure and that isn't going to have that drag.

Q. And did that relate to what you explained about the need

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to smooth out the bumps?

A. Exactly.

MR. SABER: I have no further questions, your Honor.

MS. ELDERKIN: Your Honor, if we could approach to put some exhibits on the bench for Dr. Burkhart?

THE COURT: Yes.

CROSS-EXAMINATION BY MS. ELDERKIN:

Q. Good morning, Dr. Burkhart. My name is Dianne Elderkin.

A. Good morning.

Q. Now, Dr. Burkhart, you weren't retained as an expert in this case by Arthrex, were you?

A. No.

Q. And you did not put in an expert report to advise the parties of your expert opinions before the litigation, did you?

A. No, I did not.

Q. Now, you testified that you tested an uncoated FiberWire prototype, but the prototype you tested was actually a prototype that was made of all PE, wasn't it?

A. My understanding, it was the ultrahigh molecular weight polyethylene.

Q. It had no PET in it, did it?

A. That's my understanding.

Q. And you found that that all PE suture did not have good

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation, *et al.* Defendants.	)	Civil Action No. 04-12457 PBS

DECLARATION OF CHARLES W. SABER, ESQ.

1. My name is Charles W. Saber. I am a partner with the law firm Dickstein Shapiro LLP located at 1825 Eye Street, N.W., Washington, DC 20006. I am counsel for Defendants Arthrex, Inc. and Pearsalls, Ltd. in the above-captioned matter.

2. On July 6, 2007, I participated in a meet and confer with counsel for DePuy Mitek. During the meet and confer, I explained to DePuy Mitek why Defendants believe it is necessary to have Dr. Burkhart listed as a "maybe" witness on Defendants' trial witness list. Specifically, I explained to counsel that Defendants intended to use Dr. Burkhart, if necessary, to respond to DePuy Mitek's reliance on Dr. Burkhart's role in the development of FiberWire, a role which DePuy Mitek raised after the close of fact discovery.

3. During the July 6, 2007 meet and confer, I offered to remove Dr. Burkhart from Defendants witness list if DePuy Mitek would agree not to rely on his role. DePuy Mitek rejected that offer.

4. During the July 6, 2007 meet and confer, I reminded DePuy Mitek that it had already entered into an agreement in the Joint Case Management Statement by which a witness who is to

be called at trial will be made available for deposition to the extent the witness has not yet been deposed in the case. DePuy Mitek disagreed that those were the terms of the agreement.

5. Also during the July 6, 2007 meet and confer, I offered to make Dr. Burkhart available for deposition at a mutually convenient place and time. More specifically, I offered to make Dr. Burkhart available for deposition in Boston if DePuy Mitek made his role relevant. That way, DePuy Mitek would not have to take his deposition unless it became evident that his testimony would be necessary. When DePuy Mitek rejected that offer, I stated that I would contact Dr. Burkhart to arrange a date before trial. I told DePuy Mitek's attorneys that either method was acceptable. I left the choice to them. DePuy Mitek rejected that offer and indicated that they would file the motion.

6. During the July 6, 2007 meet and confer, I also informed DePuy Mitek that neither Dr. Burkhart nor Mr. Benavitz were being called by Defendants to testify as an expert.

7. During the July 6, 2007 meet and confer, I also informed DePuy Mitek that the reason why Mr. Benavitz was on Defendants' witness list was because he is currently the person at Arthrex with direct responsibility for promoting and marketing FiberWire suture.

8. During the July 6, 2007 meet and confer, I also offered to make Mr. Benavitz available for deposition in Naples, Florida, on or about July 17, 2007, the same location and date DePuy Mitek would be taking the deposition of another one of Defendants' witnesses.

I hereby declare under penalty of perjury that the foregoing is true and correct.

Executed on: 7/16/07

Charles W. Saber

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

EXPERT REPORT OF ROBERT T. BURKS, M.D.

1. I am an orthopaedic surgeon with the University of Utah Orthopaedic Center. My office is at 590 Wakara Way, Salt Lake City, Utah 84108. I have been practicing for more than 23 years.

2. I received my M.D. from St. Louis University in 1974. I completed a residency in Orthopaedics at the University of California at San Diego in 1983. I completed a knee and sports medicine fellowship at Kaiser Permanente Hospital in San Diego in 1983, and sabbatical at Steadman Hawkins in Vail, Colorado in 1995

3. I am a Professor and Mary Scowcroft Peery Presidential Endowed Chair at the University of Utah Health Sciences Center. I am also the Director of Sports Medicine and Head Physician at the University of Utah. My curriculum vitae are attached as Exhibit 1.

4. My specialties include arthroscopy of the shoulder, knee and ankle, and ligament reconstruction. My research interests include patella stability, cartilage defects, tendon healing to bone.

5. I have reviewed Dr. Fenton's report and I understand he may provide testimony on certain subjects including human anatomy, surgical techniques and surgical devices. I may also provide testimony on these same subjects.

6. I may describe the characteristics of a surgical suture that are generally important to an orthopaedic surgeon. I may also describe the specific features of FiberWire that I find beneficial in my practice.

7. I have been using FiberWire suture in my surgical procedures since 2001. Most of my subjective use of FiberWire occurs during surgery and in the surgical environment, FiberWire is generally wet.

8. Sometime in February 2006, I was contacted by attorneys for Arthrex, Inc. and asked to conduct a tactile feel analysis as well as a knot tie-down analysis of coated and uncoated FiberWire suture. I agreed to conduct the analysis.

9. In March 2006, I received two samples of suture labeled "suture A" and "suture B." Each sample was on a spool and was approximately 3 meters in length. I was told by Arthrex's attorneys that one sample was coated US No. 2 FiberWire and that the other sample was uncoated US No. 2 FiberWire, however, I was not told which sample was coated and which was uncoated.